

viscosity of at least about 10,000 poise under oscillation stress in the range of about 0 to 5,000 (dyne/cm²) and has an initial complex viscosity of greater than about 15,000 poise.

7. (Amended) A method of making a ringing nanogel comprising the steps of combining an oil phase, a water phase, an emulsifier, and a silicone component to make an oil-in-water emulsion wherein the silicone component and the oil phase are at least about 20 percent by weight of the composition and are at least about 5 times the amount of the emulsifier, and subjecting the oil-in-water emulsion to a high shear/pressure treatment at least two consecutive times.

8. (Amended) The method of claim 7 wherein the emulsion is subjected to the high shear/pressure treatment three times.

A3 11. (Amended) The method of claim 7 further comprising no greater than about 8 percent by weight of the composition of an emulsifier.

A4 13. (Amended) The method of claim 7 wherein the oil phase is a hydrocarbon oil.

A5 16. (Amended) A ringing nanogel composition prepared according to the method of claim 7 having less than about 8 percent by weight of the composition of an emulsifier.

✓ Cancel Claim 12.

REMARKS

§112 Rejection, first and second paragraphs

The Examiner rejects Claims 2 to 6, 11, 12, and 16 under 35 U.S.C. §112, first paragraph. Claims 7 and 8 are amended to specify that the oil-in-water emulsion is subjected to a high shear/pressure treatment, and therefore, these claims are definite and clear. This amendment is supported by the specification at page 6, [00018]. In addition, the Examiner finds that Claim 13 recites a limitation of "the pre-emulsion" in Claim 7 and lacks antecedent basis. This claim has been amended to remove the reference to the pre-emulsion. No new matter is added in any of the amendments.

Finally, Claims 2 to 6, 11, 12, and 16 have been amended to specify that the amount of the emulsifier is not greater than 8 percent. Support for this amendment is found in the present specification

at page 10, [00028] wherein it sets forth that some surfactants act as emulsifiers; but that preferably, the emulsifiers are no greater than 8 percent in the nanogels of the present invention. The Examiner's mistaken reliance on Bungard et al. (U.S. Pat. No. 6,045,781, hereinafter "the '781 reference") for stating that cyclomethicone is a silicone emulsifier is founded in the fact that there appears to be no such statement in the '781 reference. At column 1, lines 26 to 30, it is explained in the '781 reference that products using a silicone emulsifier comprise an oil phase of mainly cyclomethicone. This is not a statement that cyclomethicone is an emulsifier. Further, at column 3, lines 5 to 6, the '781 reference presents an emulsifier of cyclomethicone and dimethicone copolyol. However, this is still not a statement that cyclomethicone, *per se*, is an emulsifier. Rather, it is a combination of dimethicone copolyol as the emulsifier and cyclomethicone as the oil phase. Thus, this is not a statement that cyclomethicone is an emulsifier. The present specification also recognizes the utility of silicone emulsifiers like dimethicone copolyol at page 10, [00028]. Finally, the Examiner has failed to point out exactly where in the '781 reference such a statement is in fact made. Therefore, based on Applicants' review of the '781 reference, it is asserted that such a statement is not made with respect to cyclomethicone, and that, therefore, the Examiner's reliance on the '781 reference for such a proposition is misplaced. Thus, Applicants request that the Examiner's rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

The Examiner rejects Claims 1 to 16 under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, Claims 1, 6, and 9, containing the term "difference in complex viscosity" is considered by the Examiner to be vague and indefinite because the term is not explained in the specification nor is its meaning apparent to one of ordinary skill in the art. To begin, it is noted that the term "difference in complex viscosity" is further defined in the claims in relation to a range between 0 and 5,000 (dyne/cm²). The difference in complex viscosity in the specified range is undoubtedly apparent to one of ordinary skill in the art as this is a basic mathematical expression. The meaning of the term "difference in complex viscosity in the range between 0 and 5,000 (dyne/cm²)" is to subtract the complex viscosity value at 5,000 (dyne/cm²) from the complex viscosity value at 0 (dyne/cm²). The meaning of subtraction is to find the difference. This is demonstrated by the California Standards for First Grade Math, a copy of which is attached herewith, wherein at Section 2.5 it provides that first grade students are expected to know how to demonstrate the meaning of subtraction by finding the difference. Certainly, if first graders know the meaning of "the difference", one of ordinary skill in the art would as well as it pertains to the difference in complex viscosity in the range of 0 to 5,000 (dyne/cm²), and thus, this term is clear and definite.

§103 Rejection

Claims 1 to 6, and 16 are rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 4,026,818, "the Claudelli reference" in view of U.S. Patent No. 6,120,778; "the Simonnet reference." Specifically, the Examiner alleges the following in regards to the cited references.

Claudelli teaches transparent ringing gels for cosmetic use comprising mineral oil, water, and 5 to 9 percent by weight of (2 ethyl 1,3-dihydroxy) 2-propyl oleamide. . . . The reference is silent as to the actual value of the viscosity of the ringing gel. . . . Claudelli is silent as to the size of the oil globules in the composition and also lacks the teaching of using silicone oil in the emulsion.

Simonnet teaches oil-in-water nanoemulsions based on silicone surfactants wherein the oil globules have a mean size of less than 100 nm. . . . Simonnet teaches the process of producing the invention by high-pressure homogenization . . .

It would have been obvious to one of ordinary skill in this art at the time the invention was made to have modified the composition of Claudelli by incorporating silicone phase in the emulsion and applying high shear force to produce oil-in-water nanoemulsion gel, as suggested by Simonnet, because of the expectation of successfully producing a transparent gel composition with large amount [*sic*] oil with enhanced penetration action of active components into the skin.

Claudelli and Simonnet References

Pursuant to 35 U.S.C. §103, a *prima facie* case of obviousness requires, *inter alia*, establishing that prior art reference(s) teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *In re Kotzab*, 55 USPQ2d 1313, 1316 (CAFC 2000); *see In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Neither the Claudelli reference nor the Simonnet reference, alone or in combination, teaches or suggests an oil-in-water nanogel having an oil phase and silicone component that is at least 5 times the amount of the emulsifier as the claims of the present invention are amended. Support for this amendment is found in the present specification at page 8, [00022] wherein the amount of oil phase, including the silicone component, is specified as being present in an amount at least 20 percent of the composition, and is high in comparison with the emulsifier, at least 5 times as great as the amount of the emulsifier. The present invention, as amended, contains an oil phase and a silicone component that are self-structured such that the resulting ringing nanogel has a difference in complex viscosity of at least about 10,000 poise under oscillation stress in the

range of about 0 to 5,000 (dyne/cm²). The nanogels of the present invention upon application to the skin feel pleasantly smooth at first and then transitions to a wet-like feel that is refreshing on the skin. However, because the composition is a gel, the consistency is not thin and drippy like water, and it is not tacky like other gels. This feeling and consistency is surprising especially since it is achieved with a low level of emulsifiers in comparison with the oil phase and the silicone component. This is not taught or suggested by the cited references. not claimed

reference? included anyway The Claudelli reference, as the Examiner points out, fails to teach or suggest a silicone component, and therefore, alone fails to teach or suggest the nanogels of the present invention. It is the Examiner's contention that the Simonnet reference remedies this defect because the Simonnet nanoemulsions contain silicone surfactants. However, it is not the silicone surfactants taught by the Simonnet reference, *per se*, that could possibly fill the void of the Claudelli reference, but rather the inclusion of volatile or non-volatile silicone oils as the oily phase of the Simonnet compositions as taught at column 3, lines 46 to 48. The Simonnet reference, however, does not fill this void because although the oil phase of the Simonnet reference can be a silicone oil, the Simonnet reference fails to teach or suggest a separate oil phase from that of the silicone oil, like that of the present invention, and therefore, the Simonnet reference, alone fails to teach the present invention.

The combination of the Claudelli and the Simonnet references, like the individual references themselves, fails to teach or suggest the present invention. Neither reference teaches or suggests a combination of an oil phase and a silicone component that is greater than at least about 20 percent of the composition, and that is at least about 5 times the amount of the emulsifier in the composition. To start, there is no motivation in either reference that would lead one of ordinary skill in the art to make a nanoemulsion having a separate oil phase and a separate silicone component. Next, there is no teaching or suggestion in either reference to make a nanocmulsion that contains the high amounts of the oil phase and the silicone component in comparison with the emulsifier in the composition. The examples in the Simonnet reference have between 4.5 and 5.0 percent silicone surfactant, and the oil phase is between 12 and 15 percent. Thus, the oil phase is only to about 2.4 (12/5) to 3.3 (15/4.5) times the surfactant. Therefore, the Simonnet reference fails to teach or suggest the present invention having an oil phase, including the silicone component, that is at least about 5 times the emulsifier. Similarly, this is not taught or suggested by the Claudelli reference which does not even mention a silicone component.

Because neither the cited references alone nor in combination would lead one of ordinary skill in the art to the compositions of the present invention, as amended, a *prima facie* case of obviousness has not been established. For the reasons stated above, Applicants request that the Examiner's rejection be withdrawn as Claims 1 to 6, and 16 of the present application, as amended, satisfy the requirements of 35 U.S.C. §103(a).

Claudelli, Simonnet, and Kakoki References

The Examiner finds that Claims 7 to 15 are obvious over the Simonnet and Claudelli references as discussed above and further in view of Kakoki et al. (U.S. Patent No. 5,162,377, "the Kakoki reference.") Specifically, the Examiner finds that the Simonnet and Claudelli references fail to explicitly teach a shearing process as described in Claims 7 and 8, but that the Kakoki reference teaches a high shearing treatment that is carried out by high-pressure homogenization with a Microfluidizer under a pressure of 500 psi or more. However, the Kakoki reference fails to teach or suggest the treatment of an oil phase, a water phase, and a silicone component where the oil phase and the silicone component comprise at least about 20 percent and comprise collectively at least about 5 times the amount of emulsifier. Therefore, the combination of these references fails to teach or suggest the present invention, as amended.

CONCLUSION

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

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MARKED AMENDMENTS

1. (Amended) An oil-in-water nanogel composition comprising an oil phase having a mean droplet size of less than about 100 nm, an emulsifier, a water phase, and a silicone component wherein said oil phase and said silicone component are self-structured having at least about 20 percent by weight of the composition and at least about 5 times the amount of the emulsifier and the nanogel has a difference in complex viscosity of at least about 10,000 poise under oscillation stress in the range of about 0 to 5,000 (dyne/cm²).

2. (Amended) The composition of claim 1 further comprising [an] the emulsifier present in an amount no greater than about [5] 8 percent by weight of the composition.

6. (Amended) A ringing nanogel composition comprising an oil phase, a water phase, a silicone component, and less than about [5] 8 percent by weight of the composition of an emulsifier, wherein said oil phase and said silicone component are having at least about 20 percent by weight of the composition and at least about 5 times the amount of the emulsifier self-structured and has a difference in complex viscosity of at least about 10,000 poise under oscillation stress in the range of about 0 to 5,000 (dyne/cm²) and has an initial complex viscosity of greater than about 15,000 poise.

7. (Amended) A method of making a ringing nanogel comprising the steps of combining an oil phase, a water phase, an emulsifier, and a silicone component to make an oil-in-water emulsion[, shearing] wherein the silicone component and the oil phase are at least about 20 percent by weight of the composition and are at least about 5 times the amount of the emulsifier, and subjecting the oil-in-water emulsion to a high shear/pressure treatment at least two consecutive times.

8. (Amended) The method of claim [6] 7 wherein the emulsion is [sheared] subjected to the high shear/pressure treatment three times.

11. (Amended) The method of claim 7 further comprising no greater than about [5] 8 percent by weight of the composition of an emulsifier.

13. (Amended) The method of claim 7 wherein the oil phase [of the pre-emulsion] is a hydrocarbon oil.

16. (Amended) A ringed nanogel composition prepared according to the method of claim 7 having less than about [5] 8 percent by weight of the composition of an emulsifier.

Cancel Claim 12

SCORE Mathematics - California Standards

GRADE 1

By the end of grade one, students understand and use the concept of "ones" and "tens" in the place value number system. Students add and subtract small numbers with ease. They measure with simple units and locate objects in space. They describe data and analyze and solve simple problem situations.

Number Sense

1.0 Students understand and use numbers up to 100:

1.1 Count, read, and write whole numbers to 100.

What's My Number?

1.2 Compare and order whole numbers to 100 by using the symbols for less than, equal to, or greater than ($<$, $=$, $>$).

The Greedy Dog

1.3 Represent equivalent forms of the same number through the use of physical models, diagrams, and number expressions (to 20) (e.g., 8 may be represented as $4 + 4$, $5 + 3$, $2 + 2 + 2 + 2$, $10 - 2$, $11 - 3$).

1.4 Count and group objects in ones and tens (e.g., three groups of 10 and 4 equals 34 or 30 + 4).

1.5 Identify and know the value of coins and show different combinations of coins that equal the same value.

2.0 Students demonstrate the meaning of addition and subtraction and use these operations to solve problems:

2.1 Know the addition facts (sums to 20) and the corresponding subtraction facts and commit them to memory.

What's My Number?

2.2 Use the inverse relationship between addition and subtraction to solve problems.

2.3 Identify one more than, one less than, 10 more than, 10 less than a given number.

2.4 Count by 2s, 5s and 10s to 100

→ 2.5 Show the meaning of addition (putting together, increasing) and subtraction (taking away, comparing, finding the difference).

2.6 Solve addition and subtraction problems with one- and two-digit numbers (e.g., $5 + 58 = \underline{\quad}$).

What's My Number?

2.7 Find the sum of three one-digit numbers.

3.0 Students use estimation strategies in computation and problem solving that involve numbers that use the ones, tens, and hundreds places:

3.1 Make reasonable estimates when comparing larger or smaller numbers.

Algebra and Functions

1.0 Students use number sentences with operational symbols and expressions to solve problem:

1.1 Write and solve number sentences from problem situations that express relationships involving addition and subtraction.

1.2 Understand the meaning of the symbols $+$, $-$, $=$.

What's My Number?

1.3 Create problem situations that might lead to given number sentences involving addition and subtraction.

Measurement and Geometry

1.0 Students use direct comparison and nonstandard units to describe the measurements of objects:

1.1 Compare the length, weight, and volume of two or more objects by using direct comparison or a nonstandard unit.

1.2 Tell time to the nearest half hour and related time to events (e.g., before/after, shorter/longer).

The Greedy Dog

2.0 Students identify common geometric figures, classify them by common attributes, and describe their relative position or their location in space:

2.1 Identify, describe, and compare triangles, rectangles, squares, and circles, including the

faces of three-dimensional objects.

2.2 Classify familiar plane and solid objects by common attributes, such as color, position, shape, size, roundness, or number of corners, and explain which attributes are being used for classification.

2.3 Give and follow directions about location.

2.4 Arrange and describe objects in space by proximity, position, and direction (e.g., near, far, below, above, up, down, behind, in front of, next to, left or right of).

Statistics, Data Analysis, and Probability

1.0 Students organize, represent, and compare data by category on simple graphs and charts:

1.1 Sort objects and data by common attributes and describe the categories.

1.2 Represent and compare data (e.g., largest, smallest, most often, least often) by using pictures, bar graphs, tally charts and picture graphs.

2.0 Students sort objects and create and describe patterns by numbers, shape, size, rhythm, or color:

2.1 Describe, extend, and explain ways to get to a next element in simple repeating patterns (e.g., rhythmic, numeric, color, and shape).

Mathematical Reasoning

1.0 Students make decisions about how to set up a problem:

1.1 Determine the approach, materials, and strategies to be used.

1.2 Use tools, such as manipulatives or sketches, to model problems.

The Greedy Dog

2.0 Students solve problems and justify their reasoning:

2.1 Explain the reasoning used and justify the procedures selected.

2.2 Make precise calculations and check the validity of the results from the context of the problem.

3.0 Students note connections between one problem and another.

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